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EXAMINER

ZEMAN, MARY K

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 05/05/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/976,054

Applicant(s)

CHEIKH ET AL.

Examiner

Mary K Zeman

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 19 March 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 12-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 12 and 14-19 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Claims 1 and 12-19 are pending in this application. Claims 12-19 are newly added. Claims 2-11 have been canceled.

Applicant's arguments filed 3/19/03 have been fully considered but they are not completely persuasive. Any rejection not repeated below has been withdrawn.

### ***Rejections Maintained***

Claims 1 remains rejected and new claims 12 and 14-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *To the extent this rejection applies to new claims it is necessitated by Applicant's amendment.*

The claims are drawn to isolated polynucleotides encoding a particular type of enzyme which comprise SEQ ID NO: 5, or variations thereof, having various amounts of homology, or ability to hybridize to SEQ ID NO: 5. The claims use "open" claim language which include the addition or insertion of other sequences, and read upon genomic sequences comprising promoters, enhancers, introns, etc. The claims do not require that the claimed polynucleotides have the recited enzymatic activity.

Applicant argues that the disclosure of a single short sequence is a full written description of the genus being claimed. Applicant argues that the specification provides ample description of the claimed genus of polynucleotides, in that the disclosed polynucleotide is adequate description of each genus for each polynucleotide being claimed. Applicant cites various pieces of case law which do not refer to polynucleotides, or the particular fact pattern at hand, and are thus non-persuasive. Applicant argues that one of skill in the art would not have trouble identifying other members of the claimed genus, and that the law does not require that each and every member of a claimed genus does not have to be literally disclosed. These arguments are not persuasive.

There is no description of an isolated maize or soybean polynucleotide which is a full length polynucleotide comprising an open reading frame which would encode a full length enzyme. *No such embodiments exist in the specification.* Therefore, this genus lacks written

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description. Applicant is *not* in possession of any polynucleotides which encode a maize or soybean APRT enzyme. Therefore, the disclosure is deficient, and the claims lack adequate description.

As the specification does not disclose a polynucleotide which encodes an APRT enzyme, it further does not disclose any variants of the non-existent sequence. Polynucleotides having varying levels of homology to a non-existing sequence (a polynucleotide encoding a maize or soybean APRT enzyme) do not exist, nor would one of skill in the art be able to predict or determine what they should be. Nor would one of skill in the art be able to readily identify polynucleotides which would hybridize to the non-existent full length sequence.

The specification discloses SEQ ID NO: 5 which corresponds to a short fragment of a cDNA asserted to encode a species of adenine phosphoribosyltransferase. This sequence is 440 base pairs in length, *and comprises at least 10% or about 40 unknown residues*. The entire reading frame or full length cDNA for the enzyme is not disclosed. The short sequence of SEQ ID NO: 5 is insufficient to be the entire reading frame of the enzyme, and this sequence contains a significant amount of unknown residues, therefore no species of the full enzyme are disclosed in the specification. The specification does not disclose what function or activity is encoded in any of the *short* EST sequences. As set forth herein, these sequences are too small to encode the entire enzyme such that one of skill in the art would be able to determine if other sequences could encode the same asserted functions. The specification does not identify which portions of the full length gene these elected sequences correspond to, nor does the specification disclose if any shorter sequences would be expected to encode any function of the enzyme. One of skill in the art would not be able to determine what fragments, and mutants or alleles would fall within the scope of the claims, or even what the unknown residues should be in the full length sequence.

None of these sequences encompassed by the claims meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claims.

Claims 1 remains rejected and new claims 18 and 19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly

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connected, to make and/or use the invention. *To the extent this rejection is newly applied, it is necessitated by Applicant's amendment.*

The claims are drawn to isolated polynucleotides encoding maize or soybean enzymes, particularly adenine phosphoribosyltransferase, (APRT) and fragments thereof. The elected sequence corresponding to the elected enzyme is SEQ ID NO: 5. SEQ ID NO: 5 is 440 base pairs in length with approximately 10% unknown residues. Claims 1, 18 and 19 set forth that the isolated polynucleotides encode maize or soybean APRT enzymes.

Applicant argues that given the short polynucleotide disclosed, and general cloning methods known in the art at the time the invention was made that it would not require undue experimentation to produce polynucleotides encoding maize or soybean APRT enzymes. Applicant asserts that the examiner has not met her burden for the establishment of undue experimentation, and asserts that the Wands factors would lead to a differing conclusion than that set forth by the Examiner. Applicant argues that mere, routine hybridization experiments would be enough to obtain the claimed invention, and points to several textbook type references in that regard. Applicant's arguments cannot take the place of evidence, and Applicant has not pointed to the specification for similar teachings and instructions on how to obtain the claimed polynucleotides such that the burden of enablement is satisfied. Applicant's arguments with regard to the teaching in the specification actually point to generic teachings about potential methods to isolate any polynucleotide, and is not pointed to SEQ ID NO: 5, nor does it address the difficulties documented by the examiner in the cloning and identification of related genes. Applicant discounts the difficulties documented in the prior art (Moffatt) without providing evidence to support the assertion. Applicant has not addressed the high amount of unknown residues in the sequence, and has not addressed how this would influence the further cloning and characterization of the claimed sequences. The specification does not set forth how one of skill in the art would overcome this issue. This would be expected to increase the difficulty in obtaining the claimed sequences, as one does not know what those bases should be. This influences choices of primers and probes, hybridization conditions or PCR conditions, none of which is specifically addressed in the disclosure. Applicant has not provided evidence wherein the inventors or one of skill in the art has obtained a sequence meeting the limitation of claim 1 wherein only the guidance in the specification was used. Such later produced evidence could be

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persuasive, as long as it clearly follows the teachings of the specification and does not use techniques, information or procedures which go beyond the teaching in the specification. The Examiner has provided sound scientific reasoning, with supporting documentation, meeting the legal burden.

### *Conclusion*

No claim is allowed.

Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028.

Official fax numbers for this Art Unit are: (703) 308-4242, (703) 872-9306. An *unofficial* fax number, direct to the Examiner is (703) 746 5279. Please call prior to use of this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the TC1600 Receptionist whose telephone number is (703) 308-0196.

  
MARY K. ZEMAN  
PRIMARY EXAMINER

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